

AMENDMENT AND RESPONSE TO OFFICE ACTION

Remarks

Applicants thank the Examiner for her helpful remarks during the telephone interview with Applicants' representative on March 13, 2008. Applicants have incorporated language suggested by the Examiner during the interview to further distinguish the prior art from the claimed device.

Rejection Under 35 U.S.C. §§ 102/103

Claims 1-6 and 8-10 were rejected under 35 U.S.C. § 102(b) as being anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as obvious over U.S. Patent No. 6,224,573 to Yeager *et al.* ("Yeager"). Applicants respectfully traverse this rejection.

Amendments to Claims 1 and 6

The claims have been amended to further distinguish the claimed applicator and method from Yeager. Independent claims 1 and 6, as amended, specify that the applicator barrel contains a barrier proximal to the opening and that the plunger is insertable until the barrier. Support for this amendment can be found in the specification as originally filed at page 4, lines 4-6 and in Figure 2D. This amendment clarifies that the plunger is insertable for the length of the applicator barrel until the plunger reaches the barrier, which is proximal to the opening at the end of the applicator barrel.

Yeager

Yeager's device is structurally distinct from the claimed vaginal or rectal applicator.

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Yeager discloses a disposable applicator for dispensing a desired quantity of a substantially non-runny medicament. As shown in Figures 5-7, the device contains a housing (14) which has a barrel portion (47). The barrel portion includes a generally tapered tubular wall (48) defining a housing chamber (50). As shown in Figures 2 and 7, the term "housing chamber (50)" refers to the entire space inside the barrel portion (47) (*see also* col. 6, lines 4-6). The dispensing chamber or passageway (84) (col. 4, lines 62) is external to the housing chamber (50) (*see* Figure 7). Thus, Yeager's housing chamber does not comprise a medication chamber at its proximal end, as required by independent claims 1 and 6.

Further, Yeager's device is not designed to be breach filled, as required by the method claims (*see e.g.* claim 6). In Yeager's device, the plunger only fits in the housing chamber (50). It does not fit in the dispensing chamber or passageway (84). Thus, if the dispensing chamber or passageway (84) was filled with medicament without filling the housing chamber (i.e. breach-filled), there would be no means for dispensing the medicament from the applicator since the plunger does not fit in the dispensing chamber or passageway (84).

The independent claims have been amended to specify that the applicator barrel contains a barrier proximal to the opening and that the plunger is insertable for the length of the applicator barrel until the plunger reaches the barrier. In contrast, Yeager's applicator is designed so that the plunger only fits in the housing chamber. The plunger is not insertable in the dispensing chamber or passageway, and therefore cannot travel until the opening of the device. Further,

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Yeager's device does not contain a barrier proximal to the opening. Therefore Yeager does not disclose the claimed device.

Further, Yeager teaches away from an applicator suitable for breech filling. The large opening in Yeager's device is at the proximal end of the device, while the narrow opening, through which the medicament is expelled and delivered to a patient, is located at the distal end of the device (col. 3, lines 65-67). Yeager indicates that his design, which requires placing the medicament in through the large opening at the proximal end, is well-suited for automated filling (*see* col. 5, lines 62-65). As noted above, even assuming one succeeded in filling the dispensing chamber or passageway (84) through the narrow opening, one could not then deliver the medicament through the opening at the distal end since the plunger is not able to be depressed within the dispensing chamber or passageway (84). Therefore it would not have been obvious to one of ordinary skill in the art to modify Yeager's device so that one could fill and empty the device through the narrow opening at the distal end of the device. Therefore, the claimed applicator and method of transvaginal or transrectal drug delivery are non-obvious in view of Yeager.

Additional amendments to the claims

Dependent claim 10 has been amended to refer to the barrier, in view of the amendment to independent claim 6.

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Applicants believe that this amendment places the claims in condition for allowance. However, in the event that the Examiner has further objections to the claims, Applicants respectfully request a telephone interview with the Examiner.

Allowance of claims 1-6 and 8-10, as amended, is respectfully solicited.

Respectfully submitted,

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